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10/665,343

09/18/2003

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MEGAN ANNE DIEHL and EILEEN FLECK WARWICK

Appellants

Appeal 2008-5426
Application 10/665,343
Technology Center 1600

Decided: November 21, 2008

Before RICHARD E. SCHAFER, SALLY GARDNER LANE, and JAMES T. MOORE, *Administrative Patent Judges*.

Additional views filed by MOORE, *Administrative Patent Judge*, in which SCHAFER, *Administrative Patent Judge*, joins.

Opinion for the board filed by LANE, *Administrative Patent Judge*.

DECISION ON APPEAL

I. STATEMENT OF THE CASE

The appeal, under 35 U.S.C. § 134, is from a Final Rejection of claims 1, 3, and 7-12. Claims 2 and 4-6 have been cancelled (App. Br. 6). We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

The application was filed September 18, 2003. The real party in interest is said to be Rohm and Haas Company. (App. Br. 4).

Appellants claim a microbicidal composition comprising 2-methyl-3-isothiazolone (“MIT”) and a second component chosen from a group of listed chemicals.

The Examiner relied on Antoni-Zimmermann et al., U.S. Patent 6,361,788 (“Antoni-Zimmermann”), which issued March 26, 2002. Appellants did not argue against the prior art status of this reference.

The Examiner rejected claims 1, 3, and 7-12 under 35 U.S.C. § 103(a) over Antoni-Zimmermann. Appellants did not argue for the patentability of any of the claims separately. We review claim 1 as a representative claim. *See* Bd. R. 37(c)(1)(vii). Claims 2 and 4-6 have been cancelled. (App. Br. 6).

II. ISSUE

The Examiner asserted “[t]he reference teaches the synergistic combination of 2-methylisothiazoline and various other active biocidal substances which embraces Applicant’s claimed invention.” (Ans. 4). Appellants contend that “Antoni-Zimmerman does not demonstrate that the combination claimed by Appellants are synergistic at any ratio.” (App. Br. 11). Have Appellants shown that the combination, in the claimed ratios, demonstrates an unexpected result for the entire scope of the claims?

III. FINDINGS OF FACT

The record supports the following findings of fact as well as any other findings of fact set forth in this opinion, by at least a preponderance of the evidence.

1. Appellants’ claim 1 recites:

A microbicidal composition comprising a synergistic mixture;
the first component of which is 2-methyl-3-isothiazolone [“MIT”], and
the second component of which is one or more commercial microbicides selected from the group consisting of
benzoic acid,
sorbic acid,
1,2-dibromo-2,4-dicyanobutane,
1,3 dimethylol-5,5-dimethylhydantoin,
phenoxyethanol,
zinc pyrithione and
climbazole;
wherein a ratio of 2-methyl-3-isothiazolone [MIT] to benzoic acid is from 1/0.13 to 1/67,
a ratio of 2-methyl-3-isothiazolone [MIT] to sorbic acid is from 1/4 to 1/133,
a ratio of 2-methyl-3-isothiazolone [MIT] to 1,2-dibromo-2,4-dicyanobutane is from 1/0.4 to 1/100,
a ratio of 2-methyl-3-isothiazolone [MIT] to 1,3 dimethylol-5,5-dimethylhydantoin is from 1/0.06 to 1/80,
a ratio of 2-methyl-3-isothiazolone [MIT] to phenoxyethanol is from 1/2 to 1/800,
a ratio of 2-methyl-3-isothiazolone [MIT] to zinc pyrithione is from 1/0.0013 to 1/13, and
a ratio of 2-methyl-3-isothiazolone [MIT] to climbazole is from 1/0.05 to 1/24; and
wherein the composition is substantially free of halogenated 3 isothiazolone.¹

(App. Br. 14, Claims Appendix).

2. Appellants do not contest that Antoni-Zimmermann teaches a combination of 2-methylisothiazolin-3-one [MIT²] with compounds

¹ Claim 1 has been reformatted for clarity.

including phenylethyl alcohol, sorbic acid, benzoic acid, and 1,2-dibromo-2,4-dicyanobutane and only fails to teach the specific ratios of MIT to these “second components” claimed.

3. Tables 1-9 of Appellants’ specification are said to show that the “[t]he synergism of the combinations of the present invention was demonstrated by testing a wide range of concentrations and ratios of the compounds.” (Spec. 10, ll. 19-21).

4. Appellants’ specification reports that

[s]ynergism was determined by an industrially accepted method described by Kull, F.C.; Eisman, P.C.; Sylwestrowicz, H.D. and Mayer, R.L., in Applied Microbiology 9:538-541(1961), using the ratio determined by the formula:

$$Q_a/Q_A + Q_b/Q_B = \text{Synergy Index ("SI")}$$

wherein:

Q_A = concentration of compound A (first component) in ppm, acting alone, which produced an end point (MIC of Compound A).

Q_a = concentration of compound A in ppm, in the mixture, which produced an end point.

Q_B = concentration of compound B (second component) in ppm, acting alone, which produced an end point (MIC of Compound B).

Q_b = concentration of compound B in ppm, in the mixture, which produced an end point.

When the sum of Q_a/Q_A and Q_b/Q_B is greater than one, antagonism is indicated. When the sum is equal to one, additivity is indicated, and when less than one, synergism is

² We understand “2-methylisothiazolin-3-one” to be the same as “2-methyl-3-isothiazolone,” which is claimed.

demonstrated. The lower the **SI**, the greater the synergy shown by that particular mixture.

(Spec. 10, l. 22, through 11, l. 7).

5. Tables 1 and 3-8³ of Appellants' specification include many results that are said to indicate synergism at specific ratios and for specific microorganisms with the claimed components.

6. An SI value of less than 1.00 is said to indicate synergism, while an SI values of 1.00 or greater is said to indicate no synergism. (Spec. 11, ll. 4-7).

7. The following table compiles the results reported in those tables of compositions of MIT and claimed "second components" ("SC") that do not indicate synergism due to an SI value equal to or greater than 1.00.

Table number in specification	MIT/SC claimed	MIT/SC tested	SI	Organism
1 (SC=benzoic acid)	1/1.13 to 1/67	1/50	1.67	<i>A. niger</i> *
		1/16	1.03	<i>C. albicans</i>
3 (SC=sorbic acid)	1/4 to 1/133	1/40	1.00	<i>A. niger</i>
		1/30	1.08	<i>A. niger</i>
		1/24	1.17	<i>A. niger</i>
		1/13	1.00	<i>A. niger</i>
		1/10	1.17	<i>A. niger</i>

³ Tables 2 and 9 report the results with "second components" not recited in Appellants' claim 1.

* Indicates that all of the ratios tested within the claimed range, in the specific microorganism, had an SI value of 1.00 or greater.

Table number in specification	MIT/SC claimed	MIT/SC tested	SI	Organism
		1/8	1.25	<i>C. albicans</i> *
		1/2	1.50	<i>C. albicans</i> *
		1/100	1.07	<i>S. aureus</i>
		1/40	1.03	<i>S. aureus</i>
4 (SC=1,2-dibromo-2,4-dicyanobutane)	1/0.4 to 1/100	1/2	1.17	<i>A. niger</i> *
		1/0.5	1.67	<i>A. niger</i> *
		1/1.6	1.03	<i>C. albicans</i>
		1/1.3	1.15	<i>C. albicans</i>
		1/20	1.47	<i>S. aureus</i>
		1/4	1.03	<i>S. aureus</i>
		1/53	1.00	<i>P. aeruginosa</i>
		1/30	1.04	<i>P. aeruginosa</i>
5 (SC=1,3-dimethylol-5,5-dimethylhydantoin)	1/0.06 to 1/80	1/60	1.17	<i>A. niger</i> *
		1/10	1.33	<i>A. niger</i> *
		1/60	1.25	<i>C. albicans</i> *
		1/20	1.75	<i>C. albicans</i> *
		1/2	1.07	<i>S. aureus</i>
		1/0.8	1.03	<i>S. aureus</i>
		1/40	1.00	<i>P. aeruginosa</i>
		1/27	1.17	<i>P. aeruginosa</i>
		1/10	1.00	<i>P. aeruginosa</i>
6 (SC=phenoxyethanol)	1/2 to 1/800	1/40	1.00	<i>A. niger</i>
		1/30	1.08	<i>A. niger</i>

Table number in specification	MIT/SC claimed	MIT/SC tested	SI	Organism
		1/24	1.17	<i>A. niger</i>
		1/13	1.00	<i>A. niger</i>
		1/60	1.00	<i>C. albicans</i>
		1/40	1.13	<i>C. albicans</i>
		1/20	1.00	<i>C. albicans</i>
		1/16	1.13	<i>C. albicans</i>
		1/6.7	1.00	<i>C. albicans</i>
		1/40	1.13	<i>S. aureus</i>
		1/17	1.00	<i>S. aureus</i>
		1/400	1.00	<i>P. aeruginosa</i>
		1/267	1.17	<i>P. aeruginosa</i>
		1/100	1.00	<i>P. aeruginosa</i>
7 (SC=zinc pyrithione)	1/0.0013 to 1/13	1/0.8	1.00	<i>A. niger</i>
		1/0.6	1.08	<i>A. niger</i>
		1/0.4	1.04	<i>A. niger</i>
		1/0.27	1.00	<i>A. niger</i>
		1/0.15	1.04	<i>A. niger</i>
		1/1.2	1.00	<i>C. albicans</i>
		1/0.67	1.00	<i>C. albicans</i>
		1/0.4	1.00	<i>C. albicans</i>
		1/0.24	1.00	<i>C. albicans</i>
		1/0.13	1.00	<i>C. albicans</i>
		1/1.3	1.30	<i>S. aureus*</i>

Table number in specification	MIT/SC claimed	MIT/SC tested	SI	Organism
		1/0.5	1.80	<i>S. aureus</i> *
		1/10	1.00	<i>P. aeruginosa</i>
		1/3.3	1.00	<i>P. aeruginosa</i>
8 (SC=climbazole)	1/0.05 to 1/24	1/2.7	1.04	<i>C. albicans</i>
		1/2	1.17	<i>C. albicans</i>
		1/1.6	1.29	<i>C. albicans</i>
		1/0.53	1.02	<i>C. albicans</i>
		1/32	1.03	<i>S. aureus</i>

(Spec. 12-21).

IV. PRINCIPLES OF LAW

“[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. . . . It is well settled that a prima facie case of obviousness may be rebutted ‘where the results of optimizing a variable, which was known to be result effective, (are) unexpectedly good.’” *In re Boesch*, 617 F.2d 272, 276 (1980 C.C.P.A.) (quoting *In re Antonie*, 559 F.2d 618 (CCPA 1977)).

Appellants attempt to show an unexpected result for the claimed combination by showing an unexpected synergism. “Synergism is one factor to be considered in the ultimate determination of obviousness of the composition. However, we attribute no magic status to synergism per se since it may be expected or unexpected.” *In re Huellmantel*, 324 F.2d 998, 1003 (CCPA 1963). *See also In re Diamond*, 360 F.2d 214, 218 (CCPA

1966). Like a showing for any unexpected result, a showing of an unexpected synergism “must be commensurate in scope with the claims which the evidence is offered to support” to be persuasive. *Cf. In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983) (quoting *In re Tiffin*, 448 F.2d 791 (CCPA 1971)).

V. ANALYSIS

Appellants do not refute the Examiner’s prima facie case for the obviousness of the microbicidal composition of claim 1. Instead, they attempt to rebut it by arguing that they “have demonstrated (see pages 10-21) that their claimed biocide combinations display synergistic activity (synergy index <1) within the claimed ranges of biocide ratios, and accordingly, have demonstrated unexpected results for these biocide combinations.” (App. Br. 11). Whether or not a showing of synergism is a showing of unexpected results depends of the evidence of synergism compared to the closest prior art. *See Huellmantel*, 324 F.2d at 1003; *Luvisi*, 342 F.2d at 109-110. The examples, including the tables on pages 10-21, in Appellants’ specification purport to show “[t]he synergism of the combinations of the present invention . . . demonstrated by testing a wide range of concentrations and ratios of the compounds.” (FF 3).

Tables 1 and 3-8 report what are said to be synergistic effects for many of Appellants’ claimed compositions. However, the tables also demonstrate that Appellants’ claimed ranges of combinations are not synergistic, according to Appellants’ criteria, across the entire range of ratios claimed for all microorganisms tested. (FF 7). Appellants report a “synergism index” or SI value to demonstrate synergy. (FF 4). SI values of

less than 1.00 indicate synergy, while those equal to or greater than 1.00 do not. (FF 6). For example, Table 1 reports the effects of the combination of MIT and benzoic acid, which are claimed at a range of ratios between 1/0.13 and 1/67. When MIT and benzoic acid at a ratio of 1/50 was tested on *A. niger*, the SI value was 1.67 – indicating no synergism. (FF 7). When MIT and benzoic acid at a ratio of 1/16 was tested on *C. albicans*, the SI value was 1.03 – indicating no synergism. (*See id.*). Table 3 reports the effects of the combination of MIT and sorbic acid, which are claimed at a range of ratios between 1/4 and 1/133. When MIT and sorbic acid at ratios of 1/10, 1/13, 1/24, 1/30, and 1/40 were tested on *A. niger*, the SI value was equal to or greater than 1.00 – indicating no synergism. (*See id.*). Similar examples of nonsynergistic, claimed ratios were found in each table. (*See id.*). Thus, Appellants’ own results show that the entire claimed range does not demonstrate an SI value said to indicate synergy and that such synergy does not occur with every microorganism. These gaps in the reported synergy raise significant doubt about whether those of skill in the art would have found the specifically claimed combinations to be unexpectedly better than the combinations taught by Antoni-Zimmermann.

Appellants argued that “[a] showing of unexpected results for a composition refutes a finding of obviousness, and does not require demonstrating that the unexpected results would be obtained for every possible measurement of the composition’s properties under every possible set of conditions.” (App. Br. 12). Appellants cite *In re Chupp*, 816 F.2d 643 (Fed. Cir. 1987) in support. In *Chupp*, though, a declarant stated that he found “no evidence in the cited [prior art] patents which would lead me to expect that a novel compound such as that claimed herein . . . would have

the superior properties it has exhibited.” *Id.* at 647. In contrast, Appellants did not provide statements by one of skill in the art evaluating the results presented in their specification compared to the teachings of Antoni-Zimmermann. When rebutting a prima facie case for obviousness, when “an applicant tests less than all the cited compounds, the test must be sufficient to permit a conclusion respecting the relative effectiveness of applicant’s claimed compounds and the compounds of the closest prior art.” *In re Payne*, 606 F.2d 303, 316 (CCPA 1979). Appellants have not provided sufficient evidence to show that one of skill in the art would have concluded there was unexpected synergy over the ranges claimed and for all microorganisms.

In addition, as to for those compositions that Appellants contend did exhibit synergism, Appellant has not supplied evidence, such as a declaration from one skilled in the art, sufficient to show that unexpected synergism was demonstrated. *See Huellmantel*, 324 F.2d at 1003.

VI. CONCLUSIONS OF LAW

Appellants have not shown that the claimed combinations of first component and second components, in the claimed ratios, demonstrate unexpected results in terms of an unexpected synergy for the entire scope of the claims. Moreover, Appellants have not shown that one skilled in the art would have considered the results obtained to be unexpected. Accordingly, the Examiner did not err in rejecting claim 1 under 35 U.S.C. § 103(a) over Antoni-Zimmermann.

VII. ORDER

Upon consideration of the record and for the reasons given, the Examiner's rejection of claims 1, 3, and 7-12 under 35 U.S.C. § 103(a) over Antoni-Zimmermann is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

ADDITIONAL VIEWS by MOORE, Administrative Patent Judge joined by
SCHAFFER, Administrative Patent Judge.

I join my colleagues in the majority opinion which finds the amount of testing to be insufficient.

I also reject the argument that synergistic results automatically overcome a case of obviousness.

The Appellants are claiming “synergistic” combinations of well-known antimicrobials. They are: 2-methyl-3-isothiazolone combined with “commercial” microbicides including the likes of benzoic acid, sorbic acid, 1,2-dibromo-2,4-dicyanobutane, 1,3 dimethylol-5,5-dimethylhydantoin, phenoxyethanol, zinc pyrithione and climbazole.

The Appellants argue that “there is no reason that one skilled in the art would expect a synergistic interaction between Appellants’ claimed biocides at any ratio” (Br. at 11).

This argument raised by the appellants appears to be contrary to the evidence in the record of the level of ordinary skill in the art. It was well known in the art that the performance of antimicrobial agents may be “enhanced” by combination with one or more other antimicrobial agents. See, e.g. US 6,211,213, col. 5, ll. 61-65 (provided by Appellants in an

Information Disclosure statement of March 8, 2004 and commonly assigned to the Appellants).⁴

The Appellants are using known materials for their known functions and achieving a result which may be synergistic, but on its face appears hardly surprising to one of ordinary skill in the art having regard for known and expected synergies in mixtures of antimicrobials.

The Appellants further argue that they “have demonstrated (see pages 10-21) that their claimed biocide combinations display synergistic activity (synergy index <1) within the claimed ranges of biocide ratios, and accordingly, they have demonstrated unexpected results for these biocide combinations.” (*Id.*).

We have here an argument of counsel that synergistic activity of greater than one *per se* demonstrates unobvious results. Endorsing such a rule would eviscerate the well-established principle that properties of a claimed composition, to rebut a finding of obviousness, must be unexpected. *See In re Malagari*, 499 F.2d 1297, 1303 (CCPA 1974).

We are not provided with, for example, a convincing declaration from one of ordinary skill in the art outlining how these synergistic results were surprising and unexpected. Consequently, the proffered synergistic results

⁴ US ‘213 also described various molar ratios of benzoic acids added to solutions containing 2-methyl-3-isothiazolone (Example 1 and table 1, col. 6). Those described solutions also contained 1.5 % of a halogenated isothiazolone, which is purportedly limited in the instant claims by a wherein clause reciting “substantially free of halogenated 3 isothiazolone.” The Appellants have defined “substantially free” in the instant specification as “zero or up to 3%” (Spec., 4:2). Whether the ‘213 examples may expressly teach or suggest points within the claimed ratios is not before us, however.

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lack evidence that they were unexpected, and I would affirm on this additional ground.

rvb

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